

## **REMARKS/ARGUMENTS**

Prior to entry of this amendment, claims 53-63 were pending. In the Office Action, the following requirements/objections/rejections were stated:

- A substitute specification was required because pages 35, 38 and 39 were noted to be missing from the Office copy of this continuation application.
- Amendment of the specification was requested to indicate that the acronym “IVUS” is a trademark.
- Claim 63 was rejected under 35 U.S.C. §112, second paragraph, on grounds that the acronym IVUS constitutes a trademark.
- Claims 53, 58, 60 and 61 were rejected under 35 U.S.C. §102 as being anticipated by United States Patent No. 4,905,667 (Foerster et al.).
- Claims 54 and 55 were rejected under 35 U.S.C. §103(a) as being obvious over Foerster et al. in view of United States Patent No. 5,331,947 (Shutrmann).
- Claims 56 and 57 were rejected under 35 U.S.C. §103(a) as being obvious over Foerster et al. in view of Shutrmann and United States Patent No. 6,010,480 (Abele).
- Claims 59 and 63 were rejected under 35 U.S.C. §103(a) as being obvious over Foerster et al. in view of Shutrmann and United States Patent No. 5,345,940 (Seward et al.).

Applicant responds to each of the above-summarized requirements/objections and rejections, as follows:

**Substitute Specification:**

A substitute specification that complies with 37 C.F.R. 1.125(a) is submitted herewith.

**Trademark Usage in Specification:**

Applicant respectfully submits that IVUS is a well known acronym for the generic term “intravascular ultrasound.” As such, the IVUS acronym is itself generic and incapable of performing the source designating function required of a trademark.

A search of the TESS system reveals only two (2) records containing the term “IVUS.” One record is for a previously *cancelled* trademark registration (Registration No. 1705800) for a design mark that included the letters “ivus” in stylized type. The other record is for a pending trademark application (Serial No. 78/301,268) that was filed on September 16, 2003 (long after filing of the instant patent application) seeking to register the phrase “ULTIMATE IVUS” with an express disclaimer that states “no claim is made to the exclusive right to use IVUS apart from the mark as shown.” Copies of cancelled Registration No. 1705800 and pending application Serial No. 78/301,268. The Examiner will note that Registration No. 1705800 was cancelled in 2003 and application Serial No. 78/301,268 expressly disclaims any exclusive right to use the term IVUS except in combination with the word “ULTIMATE.”

Thus, no party currently holds any United States Trademark Registration for the mark IVUS. Furthermore, the record contains no evidence that any person or entity holds common law trademark rights in the word IVUS.

In view of these facts, the usage of the acronym IVUS in the specification is believed to be proper, as originally written. No amendment or trademark designation should be required.

**Rejection under 35 U.S.C. §112:**

The Office Action states that claim 63 is rejected on grounds that it contains a trademark. However, claim 63 does not contain any language that could conceivably be perceived as a trademark. Thus, it is believed that this rejection was meant to pertain to claim 62 rather than claim 63. Claim 62 did include the acronym IVUS. As explained above, IVUS is not a trademark, it is a generic term. Also, by the present amendment, claim 62 has been amended to substitute the words “intravascular ultrasound” for the IVUS acronym. Thus, this rejection is believed to have been overcome.

**Art Based Rejections:**

By the present amendment, independent claim 53 has been amended to recite a system that is useable to guide the advancement of a guidewire from a location within the lumen of a blood vessel to a location outside of that blood vessel lumen. In general, the system recited in amended claim 53 comprises 1) a catheter, 2) a tissue penetrating element and 3) a guidewire. Amended claim 53 further recites that the tissue penetrating element has a lumen, a tissue penetrating distal tip and a distal end opening. Also, amended claim 53 requires that the tissue penetrating element be alternately disposable in a) a first position wherein it is substantially within the catheter body and b) a second position wherein it assumes a predetermined curved configuration and extends out of the catheter’s opening so as to penetrate a wall of the blood vessel adjacent to the blood vessel lumen. Furthermore, claim 53 recites a guidewire that is advanceable through the tissue penetrating element when the tissue penetrating element is in its claimed “second position.” This amendment has added no new matter and is fully supported by the original specification, including but not limited to the description set forth on pages 15-19 and the accompanying figures to which it refers (note, for example, guide catheter 50 having opening 58 through which tissue penetrating element 78 is

deployed such that guidewire 79 may be advanced through the lumen of tissue penetrating element 78).

Also, by the present amendment, dependent claims 59 and 60 have been cancelled and dependent claims 54-58 and 61-63 have been amended to recite a “system” rather than a “device.”

As presently amended, independent claim 53 is patentably distinguishable, on various grounds, over all prior art of record, including Forester et al., Shturman, Abele et al. and Seward et al. For example, neither Forester et al. nor Shturman nor Abele et al. nor Seward et al. describes a catheter from which a tissue penetrating element is advanceable to a location outside the lumen in which the catheter is positioned. Rather, Forester et al., Shturman, Abele et al. and Seward et al. describe devices that are useable entirely within the lumen of the body lumen in which they are positioned or advanceable into a side branch or pre-existing opening in that blood vessel lumen. In fact, none of these prior art references teaches or even remotely suggests any intentional penetration into or through the wall of the anatomical conduit in which the catheter is positioned. Rather, these prior art references describe devices that are used to perform procedures wherein the wall of the anatomical conduit in which the device is positioned is not injured, penetrated or breached. To purposely advance a tissue penetrating element into or through the wall of a blood vessel would, indeed, be contrary to the teachings and objectives of Forester et al., Shturman, Abele et al. and Seward et al. Thus, for this reason and potentially other reasons not specifically stated here, independent claim 53 is in condition for allowance.

Dependent claims 54-58 and 61-63 further limit or add to the subject matter of independent claim 53 and, accordingly, are in condition for allowance for at least the same reasons as stated above with respect to independent claim 53.

**Conclusion:**

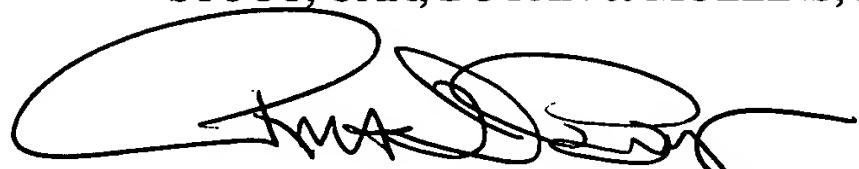
All requirements and objections to the specification have been complied with or traversed

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and all claims 53-58 and 61-63 are believed to be in condition for allowance. Accordingly, issuance of a Notice of Allowance is earnestly solicited.

Respectfully submitted,  
STOUT, UXA, BUYAN & MULLINS, LLP

Date: December 16, 2004



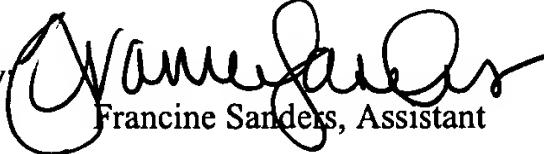
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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on December 16, 2004.

Dated: December 16, 2004

By   
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